

**STATE OF MISSOURI  
MISSOURI BOARD OF PHARMACY**

IN RE:	)	
	)	
ALEXANDER J. SMITH, R.PH.	)	
License No. 2014028409	)	Complaint No. 2018-001820
18451 Hunters Ridge Court	)	
Boonville, MO 65233.	)	

**SETTLEMENT AGREEMENT BETWEEN THE  
MISSOURI BOARD OF PHARMACY AND ALEXANDER SMITH**

Come now Alexander J. Smith, R.Ph. ("Respondent" or "Licensee") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's license to practice pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that he understands the various rights and privileges afforded him by law, including the right to a hearing of the charges against him; the right to appear and be represented by counsel; the right to have all charges against him proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against him; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against him and, subsequently, the right to a disciplinary hearing before the Board at which time he may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against his license. Being aware of these rights provided him by operation of law, Respondent knowingly and



voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to him.

Respondent acknowledges that he has received a copy of the draft Complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's license.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's license to practice pharmacy, numbered 2014028409, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

### **JOINT STIPULATION OF FACTS**

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.140, RSMo<sup>1</sup>, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Respondent Alexander J. Smith is licensed as a pharmacist under the laws of the State of Missouri, License No. 2014028409. Respondent's license was at all times relevant herein current and active.

3. At all relevant times herein, Respondent was employed as pharmacist-in-charge (PIC) at Flow's Pharmacy, 303 N. Keene St., Columbia, MO (the "Pharmacy").

4. During a routine inspection of the Pharmacy's second location on Broadway St., Columbia, MO, on March 6, 2018, Board Inspector Scott Spencer discovered that pharmacist R.H., who worked at both locations, had not submitted a Notification of Intent (NOI) to immunize to the

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<sup>1</sup> All statutory references are to the Revised Statutes of Missouri 2016 as amended unless otherwise indicated.



Board prior to administering vaccines per protocol and that R.H. was administering vaccines on an expired protocol.

5. Upon further investigation, Inspector Spencer also discovered that Respondent had been administering vaccines without a signed protocol.

6. The Pharmacy's most recent protocol for vaccine administration was effective August 1, 2017 to August 1, 2018.

7. Neither Respondent nor R.H. had signed the Pharmacy's most recent protocol.

8. A total of 24 vaccinations had been administered at the Pharmacy without a valid signed protocol between October 18, 2017 and March 8, 2018, 16 of which were administered by Respondent and eight (8) by R.H.

9. The eight (8) vaccinations administered by R.H. also were administered without having submitted an NOI to the Board for this activity.

10. Additionally, R.H. administered two (2) vaccines by prescription order at the Pharmacy without having submitted an NOI to the Board for this activity.

11. Some of Respondent's vaccine records also were incomplete in that they were missing required content such as: patient name and address, manufacturer, lot number, expiration date, route of administration, dose, anatomic site, VIS information, administering pharmacist name or initials, and documentation of notification to protocol and primary care physicians.

12. Missouri law gives a licensed pharmacist the authority to give immunizations, to wit:

1. The "practice of pharmacy" means . . . the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by a



physician for a specific patient as authorized by rule; . . . § 338.010.1, RSMo.

13. However, Missouri law imposes the following requirements in order for pharmacists to be authorized to give immunizations per protocol as set forth in 20 CSR § 2220-6.050, which provides in relevant parts:

(1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine.

\* \* \*

(4) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, must:

(F) Provide documentation of subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering vaccines; and

(G) On a yearly basis prior to administering vaccines, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

(5) Administration by Written Protocol with a Missouri Licensed Physician.

(A) A pharmacist may enter into a written protocol with a physician for the administration of vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures . . .



2. Time period of the protocol;
3. The identification of the vaccines which may be administered;
4. The identity of the patient or groups of patients to receive the authorized vaccine(s);
5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician's name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street addresses of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;
11. Record-keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it at any time.

(B) The protocol, and any subsequent amendments or alterations, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.<sup>2</sup>

(6) Record Keeping.

(A) A pharmacist administering vaccines pursuant to this rule shall maintain a record of each administration which shall include:

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;

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<sup>2</sup> All citations to 20 CSR § 2220-6.050 refer to the regulation in effect at the time of the violations.



3. The name, dose, manufacturer, lot number, and expiration date of the vaccine;
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable.

(7) Notification Requirement.

(A) A pharmacist administering vaccines authorized by Chapter 338, RSMo, shall notify the authorizing physician within seventy-two (72) hours after administration of the following:

1. The identity of the patient;
2. The identity of the vaccine(s) administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) The pharmacist shall provide a written report to the patient's primary health care provider, if different than the authorizing physician, containing the documentation required in subsection (A) of this section within fourteen (14) days of the administration.

\* \* \*

(E) Documentation that notifications required by this rule have been sent must be maintained as provided in section (6) of this rule.

14. Missouri also law imposes the following requirements in order for pharmacists to be authorized to give immunizations by prescription as set forth in 20 CSR § 2220-6.040, which provides in relevant parts:

(1) A pharmacist may administer drugs pursuant to a medical prescription order.

\* \* \*



(3) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must—

\* \* \*

(F) On a yearly basis prior to administering drugs, notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section.<sup>3</sup>

15. Pharmacist R.H. violated § 338.010.1, RSMo, 20 CSR § 2220-6.050(1), (4)(F)-(G) and (5)(A)-(B) by administering eight (8) vaccinations per protocol without a valid immunization protocol and without having submitted an NOI to engage in such activity to the Board.

16. Pharmacist R.H. violated § 338.010.1, RSMo, 20 CSR § 2220-6.040(1), (3)(F) and by administering two (2) vaccinations by medical prescription order without having submitted an NOI to engage in such activity to the Board.

17. Pharmacist R.H. violated § 338.010.1, RSMo, 20 CSR § 2220-6.050(1), and (5)(A)-(B) by administering eight (8) vaccinations per protocol without a valid immunization protocol.

18. Respondent violated § 338.010.1, RSMo, 20 CSR § 2220-6.050(6)(A) and (7)(A)-(B) and (E) by failing to include the patient name and address, manufacturer, lot number, expiration date, route of administration, dose, anatomic site, VIS information, administering pharmacist name or initials, and documentation of notification to protocol and primary care physicians in several administration records.

19. As pharmacist-in-charge, Respondent's failure to assure full compliance with state and federal pharmacy laws and regulations by staff pharmacists also is in violation of 20 CSR 2220-2.090(2)(N) and (W) which states, in pertinent part:

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<sup>3</sup> All citations to 20 CSR § 2220-6.040 refer to the regulation in effect at the time of the violations.



(2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:

\* \* \*

(N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;

\* \* \*

(W) Assure full compliance with all state and federal drug laws and rules.

### **JOINT CONCLUSIONS OF LAW**

20. Respondent's conduct is cause for disciplinary action against his license to practice pharmacy under § 338.055.2(6), and (13), RSMo, which provides:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

\* \* \*

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

\* \* \*

(13) Violation of any professional trust or confidence.



## **JOINT AGREED DISCIPLINARY ORDER**

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

A. Respondent's license, License No. 2014028409, is hereby **PUBLICLY CENSURED**.

B. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

C. Respondent, together with his heirs and assigns, and his attorneys, does hereby waive and release the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.



RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE  
LINE,

\_\_\_\_\_  
*ofs* <sup>x</sup> REQUESTS  
\_\_\_\_\_  
DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS  
SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S  
LICENSE TO PRACTICE PHARMACY.

The parties to this Agreement understand that the Board of Pharmacy will maintain this  
Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

If Respondent has requested review, Respondent and Board jointly request that the  
Administrative Hearing Commission determine whether the facts set forth herein are grounds for  
disciplining Respondent's license and issue findings of fact and conclusions of law stating that the  
facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen  
(15) days from the date the Administrative Hearing Commission determines that the Settlement  
Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set  
forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the  
Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's  
Executive Director.



RESPONDENT

Alex J. Smith  
Alexander J. Smith

Date: 8/12/2019

PETITIONER

MISSOURI BOARD OF  
PHARMACY

By:

Kimberly Grinston  
Kimberly Grinston  
Executive Director

Date:

9/19/19

NEWMAN, COMLEY & RUTH P.C.

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